

K 972286

JUL 14 1997

**Section # 2**

**Safety and Effectiveness Summary  
and  
Premarket Notification Truthful and Accurate Statement**

**Safety and effectiveness summary:**

The Non-confidential Summary of Safety and Effectiveness follows.

**Premarket Notification Truthful and Accurate Statement:**

As recommended, this statement has been placed on company letterhead and follows.

**UNIVERSAL REAGENTS, INC.**

2858 North Pennsylvania Street

Indianapolis, Indiana 46205

PHONE: (317) 926-0015

FAX: (317) 926-0014

**Non-Confidential Summary of Safety and Effectiveness**

June 18, 1997

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Universal Reagents, Inc.  
2858 N. Pennsylvania St.  
Indianapolis, IN 46205

Tel - (317) 926-0006  
Fax - (317) 926-0014

**Official contact:** Jorge Miller, Director, Coagulation Products

**Proprietary or Trade Name:** Factor deficient coagulation plasma - XI

**Common/Usual Name:** Qualitative and Quantitative Factor Deficiency Test - XI

**Classification Name:** Qualitative and Quantitative Factor Deficiency Test

**Intended device:** Factor deficient coagulation plasma - XI

**Predicate devices:** Pacific Hemostasis Factor XI - K# unknown

**Device description:** Factor deficient plasma to be free of antigen of Factor XI utilized in *in vitro* diagnostic use.

**Intended use:**

Indicated use - Factor deficient plasma, Factor - XI is a human plasma immunodepleted of the specific factor and intended for use in the quantitative determination of the specific factor levels in patients suspected of congenital or acquired deficiency of this specific coagulation protein and is performed by clotting assay.

**Environment of use:** Clinical laboratories

**Comparison to predicate devices:**

Attribute	Intended product	Pacific Hemostasis
<b>Use</b>		
Indicated for use in determination of coagulation of plasma	Yes	Yes
In vitro diagnostic use	Yes	Yes
Used as a quantitative assay	Yes	Yes
<b>Design</b>		
Factor XI deficient plasma offered	Yes	Yes

**Non-Confidential Summary of Safety and Effectiveness  
(continued)**

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**Comparison to predicate devices: (continued)**

<b>Attribute</b>	<b>Intended product</b>	<b>Pacific Hemostasis</b>
Packaging either - Frozen or Dry / lyophilized	Yes	Yes
Can be used with different instruments and reagents per manufacturer instructions	Yes	Yes
<b>Materials</b>		
Donor human plasma	Yes	Yes
Various buffers	Yes	Yes
<b>Performance Testing</b>		
Compare assay to known sample	Yes	Yes
Negative by FDA approved test for HIV 1/2 and HBsAG	Yes	Yes
Negative by FDA approved test for HCV and HIV-1ag	Yes	not known
Deficiency of relevant factor less than 1%	Yes	not known
Negative for HIV and HBsAG	Yes	Yes
Negative for HCV, HIV-1ag	Yes	not known
No inhibitor present	Yes	not known

**Differences**

The only difference is that the intended product is claimed to be negative for HCV and HIV-1ag by an FDA approved test.

Any other differences that do exist would not have a significant effect on the safety or effectiveness of the device.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
2098 Gaither Road  
Rockville MD 20850

Jorge Miller  
• Director, Coagulation Products  
Universal Reagents, Inc.  
2858 North Pennsylvania Street  
Indianapolis, Indiana 46205

JUL 14 1997

Re: K972286  
URI Factor XI  
Regulatory Class: II  
Product Code: GJT, GGP  
Dated: June 18, 1997  
Received: June 19, 1997

Dear Mr. Miller:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal Laws or Regulations.

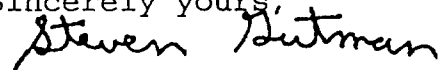
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Under the Clinical Laboratory Improvement Amendments of 1988 (CLIA-88), this device may require a CLIA complexity categorization. To determine if it does, you should contact the Centers for Disease Control and Prevention (CDC) at (770) 488-7655.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4588. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "<http://www.fda.gov/cdrh/dsmamain.html>".

Sincerely yours,



Steven I. Gutman, M.D., M.B.A.  
Director  
Division of Clinical  
Laboratory Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

JUL 14 1997

Section # 3

Labeling (continued)

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C. Indications for Use Statement

Pursuant to the Notice of 2/6/96 regarding listing of Indications for Use on a separate sheet, the following is per that request.

510(k) Number: \_\_\_\_\_ (to be assigned)

Device Name: Factor Deficient Coagulation Plasma  
Factor - XI (11)

Indications for Use:

Indicated use - This product is intended for use in the quantitative determination of factor levels in patients suspected of congenital or acquired deficiency of this coagulation protein or factor, XI.

Factor immunodeficient plasma XI is made from human plasma that has been artificially depleted. This plasma has normal levels of all other factors.

Claims - Negative per FDA approved test for HIV 1/2, HBsAG, HCV, HIV-1ag

Packaging - Frozen  
Freeze dried - Lyophilized

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)

Division of Clinical Laboratory Devices

510(k) Number 7-4092

Prescription Use  
(Per 21 CFR 801.109)

OR

Over-The-Counter Use \_\_\_\_\_

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Section # 5

Sections # 6,7

Attachments